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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,227	10/31/2003	Erik Ho Fong Wong	400.US1	1505
25533	7590	02/24/2006	EXAMINER	
PHARMACIA & UPJOHN 700 Portage Road KZO-300-104 KALAMAZOO, MI 49001			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,227	<b>Applicant(s)</b> WONG ET AL.	
	<b>Examiner</b> Rita J. Desai	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.  
 4a) Of the above claim(s) 4-8, 16-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9-15, 24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/5/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicants have elected group I, claims 1-3, 9-15 and 24-31 drawn to compounds of formula I wherein the Azabicyclo is of the formula I or IV.

### ***Claim Objections***

The claims still contain non-elected subject matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim s 13 and 15 recites the limitation "dependent from claim 12 and 14" and these are further dependent on claim 11 which is dependent on claim 2 , which has to have R2 being an lower alkyl or a substituted lower alkyl. Some of the compounds in claim 13 and claim 15 do not have R2 as an alkyl. Thus there is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

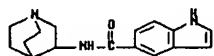
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 24, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4605652 , William Welstead 1986.

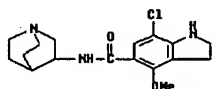
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The reference discloses the compounds of the invention. See example 22 in column 13, example 32 , 35 in column 17 and 18.



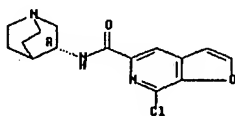
Claims 1-2, 24, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 90/06113 Pelletier et al 1990. (US4920219 and US 5063230)

The reference discloses the compounds of the invention . See page 22 example 1.



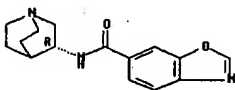
Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by CA02445467 Wishka Don et al. (same family as WO02/100857)

See example 1 page 65 example 3 on page 69.



Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al US 6828330.

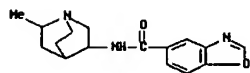
The reference clearly discloses the compounds of the invention . See examples 11, 10 in column 38 and 39 of the reference.



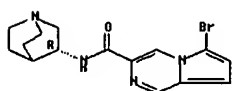
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Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by

WO 03/037896 Walker et al discloses

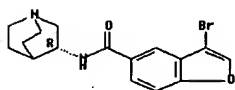


WO 03/070732 Rogers et al

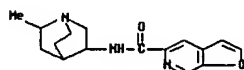


US 6894042 Walker et al and .

WO03/070731 Walker et al disclose

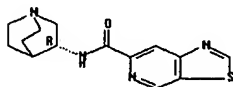


WO 2003- 029252 Walker et al discloses



The above references all disclose the compounds of the invention. WO'896 and '252 meet the limitations of claim 3.

WO 2003-022856 Wishka et al discloses



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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 9-15, 24-31 are rejected under 35 U.S.C. 103(a) as being obvious unpatentable over all the above references and WO 03/037896 Walker et al. Priority date of 10/2001.

Applicant's claims are drawn to a pharmaceutical composition with specific amount according to the body weight. Also they optionally use an anti psychotic agent.

**Determination of the scope and content of the prior art (MPEP §2141.01)**

The reference discloses similar compounds (see rejection supra) used as the same NACHR agonists.

On page 16 it discloses the different dosages all of which fall within the range of the applicants ranges. And given as

<p>The pharmaceutical composition is administered to deliver a compound of the present invention in an amount of from about 0.001 to about 100 mg/kg of body weight of said mammal per day. The pharmaceutical composition is also administered to deliver a compound of the present invention in an amount of from about 0.1 to about 50 mg/kg of body weight of said mammal per day.</p>
--

The reference also clearly uses the compound with other anti-psychotic agents on page 12.

See below:-

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15 In another aspect, the invention includes treating a mammal suffering from schizophrenia or psychosis by administering compounds of Formula I in conjunction with antipsychotic drugs (also called anti-psychotic agents). The compounds of the

**Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)**

Similar compounds are disclosed in the various references and pharmaceutical compositions too.

However, the specific use of the anti-psychotic agent is only given in the WO '896 document.

**Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)**

Since similar compounds are disclosed in all the documents and use and pharmaceutical compositions are clearly disclosed in the WO reference one of skill in the art would be motivated to make similar pharmaceutical compositions with the same dosage and agents to obtain the compounds of the instant application.

Claims 1-3, 9-15, 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over all the above 102 reference and Schmitt et al US 6432975.

The reasoning is the same as those given above since the Schmitt et al also teaches similar compounds and its pharmaceutical compositions to be used as with other agents. The various dosages are also disclosed. See column 19 and 21 of the reference.

Also the reference above disclose some compounds with the alkyl substitution on the azabicyclo ring. Meeting the limitations of claim 2.

Also some of the compounds have only a hydrogen substitution, but substituting a lower alkyl for a hydrogen is considered to be obvious in the absence of a showing of unexpected results.

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***Conclusion***

The claims 1-3, 9-15, 24-31 are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

*R. Desai*  
*2/17/06*

R.D.  
February 16, 2006